

PATENT
Attorney Docket No. PC11076A US

REMARKS

I. Status

Claims 1-8 are pending in the present application. Claims 1 and 5-7 are currently amended to further clarify the meaning of the claims, as discussed in greater detail below.

Claims 1-8 stand rejected under 35 U.S.C. § 112, ¶1 with regard to enablement. Claims 1-5 and 8 stand rejected under 35 U.S.C. § 112, ¶1 with regard to the written description requirement. Claims 1-8 stand rejected under 35 U.S.C. § 112, ¶2 for various reasons discussed in greater detail below.

Notably, claim 1 is currently amended to include the proviso that when R⁴ is phenyl or pyridyl, Q is (C₁-C₆)alkyl, q is 0 or 1, R⁵ can be selected from the group consisting of carboxy(C₁-C₆)alkylaminocarbonylamino, (C₂-C₉)heteroarylaminocarbonylamino, ((C₁-C₆)alkylamino)(C₆-C₁₀)aryl(C₁-C₆)alkyl, amino(C₁-C₆)alkoxycarbonylamino, (C₁-C₆)alkyl, halo(C₁-C₆)alkyl, aminocarbonyl, ureido(C₁-C₆)alkylcarbonylamino, (C₁-C₆)alkylcarbonylamino(C₁-C₆)alkylcarbonylamino, and (C₁-C₆)alkylcarbonylamino(C₁-C₆)alkylaminocarbonylamino. Support for the proviso can be found throughout the specification as originally filed and at least at the locations specified in the table below, which is presented for the Examiner's convenience.

Moiety	R ⁴ is phenyl; Q is (C ₁ -C ₆)alkyl; q is 0 or 1	R ⁴ is pyridyl; Q is (C ₁ -C ₆)alkyl; q is 0 or 1
carboxy(C ₁ -C ₆)alkylaminocarbonylamino	page 9, line 25	page 10, line 30
(C ₂ -C ₉)heteroarylaminocarbonylamino	page 9, line 25	page 10, line 30
((C ₁ -C ₆)alkylamino)(C ₆ -C ₁₀)aryl(C ₁ -C ₆)alkyl	page 10, line 6	page 11, line 12
amino(C ₁ -C ₆)alkoxycarbonylamino	page 10, line 7	page 11, line 13
(C ₁ -C ₆)alkyl	page 10, line 14	page 11, line 20

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halo(C ₁ -C ₆)alkyl	page 10, line 14	page 11, line 20
aminocarbonyl	page 10, line 18	page 11, line 24
ureido(C ₁ -C ₆)alkylcarbonylamino	page 10, line 20	page 11, line 26
(C ₁ -C ₆)alkylcarbonylamino(C ₁ -C ₆)alkylcarbonylamino	page 10, line 20	page 11, line 26
(C ₁ -C ₆)alkylcarbonylamino(C ₁ -C ₆)alkylaminocarbonylamino	page 10, line 21	page 11, line 26

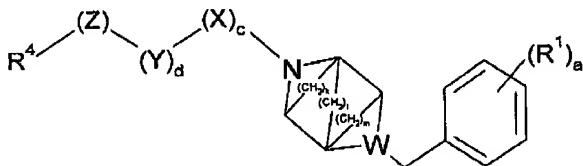
At the outset, Applicants thank the Examiner for withdrawing the following four rejections indicated at page 2 of the present Office Action: (1) the Markush rejection of claims 1-8 and 12-14; (2) the 35 U.S.C. § 112, ¶1 rejection of claims 1-14; (3) the 35 U.S.C. § 112, ¶1 rejection of claims 9-14; and (4) the 35 U.S.C. § 112, ¶2 rejection of claims 9-14.

II. Claims 1-8 Satisfy the Enablement Requirement

Claims 1-8 stand rejected under § 112, ¶1 with regard to enablement. Applicants respectfully traverse the rejection.

The Examiner asserts that claims 1-8 do not comply with the enablement requirement insofar as claim 1 defines compounds of formula I where k is 2, l is 0, and m is 0 and that the definitions of k, l, and m supposedly are not within the scope of the elected subject matter.

Claim 1 as previously amended defines in part a compound of the formula:



where k is 2, l is 0, and m is 0. As stated at page 16 of Applicants' previous Response dated May

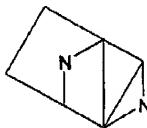
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11, 2004, claim 1 was amended to define only subject matter elected in response to a previous Restriction Requirement. In the Restriction Requirement, Applicants elected Group I (claims 1-14) drawn to compounds, compositions and method of use of the compounds of formula I where the ring formed is 3,8-diaza-bicyclo[3.2.1]octy-8-yl. As the Examiner knows, a 3,8-diaza-bicyclo[3.2.1]octy-8-yl ring has the following general structure:



In view of the elected subject matter, Applicants amended variables l and m to be 0 to indicate the presence of zero methylene groups at their respective positions. Similarly, Applicants amended variable k to be 2 to indicate the presence two methylene groups at the specified positions. The result of the amendments to k, l, and m results in the elected 3,8-diaza-bicyclo[3.2.1]octy-8-yl ring shown immediately above. Applicants previously made the indicated amendments to k, l, and m in good faith to arrive at the elected subject matter.

Nevertheless, the Examiner asserts at page 4 of the present Office Action that Applicants' amendment of k, l, and m would result in a ring having the following structure:



Apparently, the Examiner believes that when l and m are defined as zero, a covalent bond is formed. Applicants respectfully contend, however, that the Examiner's belief runs contrary to the knowledge of those of skill in the art. For example, in the ring structure shown immediately above, the carbons

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alpha to the right-hand side nitrogen are each sp^3 hybridized carbons, which are known to have bond angles of 109.5°. In the structure suggested by the Examiner, however, the bond angles are much smaller (perhaps 35°) than what those of skill in the art would expect. In fact, the ring structure presented by the Examiner suggests a chemical impossibility due to the ring strain created by the two covalent bonds. Those of skill in the art would readily recognize additional reasons why Applicants' present definitions of k, l, and m would not arrive at the ring structure suggested by the Examiner. Indeed, those of skill in the art would expect the current definitions of k, l, and m to result in the elected 3,8-diaza-bicyclo[3.2.1]octy-8-yl ring.

In view of the foregoing, claim 1 is definite. Claims 2-8 are definite at least by virtue of their direct dependency from claim 1. Thus, removal of the present rejection is respectfully requested at this time.

III. Claims 1-5 and 8 Satisfy the Written Description Requirement

Claims 1-5 and 8 stand rejected under § 112, ¶1 with regard to the written description requirement. Applicants respectfully traverse the rejection.

In particular, the Examiner asserts that Applicants' previous amendment to R⁵ to include the moieties carboxy(C₁-C₆)alkylaminocarbonylamino, (C₂-C₉)heteroarylaminocarbonylamino, ((C₁-C₆)alkylamino)(C₆-C₁₀)aryl(C₁-C₆)alkyl, amino(C₁-C₆)alkoxycarbonylamino, (C₁-C₆)alkyl, halo(C₁-C₆)alkyl, aminocarbonyl, ureido(C₁-C₆)alkylcarbonylamino, (C₁-C₆)alkylcarbonylamino(C₁-C₆)alkylcarbonylamino, and (C₁-C₆)alkylcarbonylamino(C₁-C₆)alkylaminocarbonylamino constituted new matter. Without admitting or denying the assertion, claim 1 is currently amended to delete the cited moieties from the general definition of R⁵. In that regard, the claim 1 is further

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amended to define the cited moieties by way of a proviso, as discussed above. Given the support indicated for each of the moieties, no new matter is being presented by way of the addition of the proviso to claim 1. As such, claim 1 satisfies the written description requirement. Claims 2-5 and 8 satisfy the written description requirement at least by virtue of their dependency from patentable claim 1. Thus, removal of the present rejection is currently requested at this time.

IV. Claims 1-8 Are Definite

Claims 1-8 stand rejected under § 112, ¶2 for various reasons, each of which is discussed in turn below in the order presented by the Examiner beginning at page 6 of the Office Action. Applicants respectfully traverse the rejections.

a) The Examiner asserts that claims 1-5 and 8 are indefinite with regard to the definition of R⁵ where R⁵ is the moiety cyano halo(C₁-C₆)alkoxy. Claim 1 is currently amended near the bottom of page 6 above to insert a comma between "cyano" and "halo(C₁-C₆)alkoxy" to obviate an error of a typographical nature. Such error was made inadvertently and in good faith. No new matter is being added by way of the cited amendment. As such, claim 1 is definite, and claims 2-5 and 8 are definite at least by virtue of their dependency from claim 1.

b) The Examiner asserts that there is insufficient antecedent basis for "CH" in the definition of W in claim 5. Claim 5 is currently amended to delete "or CH" to be commensurate in scope with the previously elected subject matter. The deletion of the cited subject matter is made without prejudice to pursuing such subject matter in any continuing application. No new matter is being added by way of the cited amendment. As such, claim 5 has proper antecedent basis.

c) The Examiner asserts that there is insufficient antecedent basis for "3" in the

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definition of k in claim 5. Claim 5 is currently amended to delete "or 3" to be commensurate in scope with the previously elected subject matter. The deletion of the cited subject matter is made without prejudice to pursuing such subject matter in any continuing application. No new matter is being added by way of the cited amendment. As such, claim 5 has proper antecedent basis.

d) The Examiner asserts that there is insufficient antecedent basis for "zero, zero and 2 or 3 respectively" in the definition of k, l, and m in claim 5. Claim 5 is currently amended to delete the phrase "or k, l, and m are zero, zero and 2 or 3 respectively" to be commensurate in scope with the previously elected subject matter. The deletion of the cited subject matter is made without prejudice to pursuing such subject matter in any continuing application. No new matter is being added by way of the cited amendment. As such, claim 5 has proper antecedent basis.

e) The Examiner asserts that claim 6 is indefinite with regard to the second occurrence of (C₂-C₉)heteroarylamino in the definition of R⁵. Claim 6 is currently amended for greater clarification by deleting the second occurrence of (C₂-C₉)heteroarylamino in the definition of R⁵. No new matter is being added by way of the cited amendment. As such, claim 6 is definite.

f) The Examiner asserts that claim 6 is indefinite with regard to the second occurrence of ((C₁-C₆)alkyl)₂amino(C₁-C₆)alkylcarbonylamino. Claim 6 is currently amended for greater clarification by deleting the second occurrence of ((C₁-C₆)alkyl)₂amino(C₁-C₆)alkylcarbonylamino in the definition of R⁵. No new matter is being added by way of the cited amendment. As such, claim 6 is definite.

g) The Examiner asserts that there is insufficient antecedent basis for "amino(C₁-C₆)alkoxycarbonylamino" in the definition of R₅ in claim 6. Without admitting or denying the Examiner's assertion, claim 1 is currently amended to delete the moiety "amino(C₁-

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C₆)alkoxycarbonylamino" from the general definition of R₅ in claim 1. As indicated above, however, the cited moiety is included in proviso currently added at the end of claim 1. Support for the amendment is indicated above. No new matter is being made by way of the foregoing amendment. As such, claim 6 has proper antecedent basis.

h) The Examiner asserts that claim 7 is not definite with regard to the second occurrence of (C₂-C₉)heteroarylalmino. Claim 7 is currently amended for greater clarification by deleting the second occurrence of (C₂-C₉)heteroarylalmino in the definition of R⁵. No new matter is being added by way of the cited amendment. As such, claim 7 is definite.

i) The Examiner asserts that claim 7 is indefinite with regard to the second occurrence of ((C₁-C₆)alkyl)₂amino(C₁-C₆)alkylcarbonylamino. Claim 7 is currently amended for greater clarification by deleting the second occurrence of ((C₁-C₆)alkyl)₂amino(C₁-C₆)alkylcarbonylamino in the definition of R⁵. No new matter is being added by way of the cited amendment. As such, claim 7 is definite.

j) The Examiner asserts that there is insufficient antecedent basis for "amino(C₁-C₆)alkoxycarbonylamino" in the definition of R₅ in claim 7. Without admitting or denying the Examiner's assertion, claim 1 is currently amended to delete the moiety "amino(C₁-C₆)alkoxycarbonylamino" from the general definition of R₅ in claim 1. As indicated above, however, the cited moiety is included in proviso currently added at the end of claim 1. Support for the amendment is indicated above. No new matter is being made by way of the foregoing amendment. As such, claim 7 has proper antecedent basis.

While not expressly cited by the Examiner, claim 1 is currently amended to remove the second occurrence of (C₂-C₉)heteroaryl(C₁-C₆)alkylalmino. Support for the amendment can be

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found at least at originally filed claim 1. No new matter is being made by the cited amendment.

V. Conclusion

Having addressed all outstanding issues, Applicants kindly request removal of all rejections and allowance of all pending claims at this time. To the extent the Examiner believes that it would facilitate allowance of this case, the Examiner is urged to call the undersigned at the number below.

Applicants believe that no fee is associated with the filing of this paper. However, to the extent a fee is due, the Commissioner is hereby authorized by this paper to charge any required fees or credit any overpayment to Deposit Account 16-1445.

Respectfully submitted,

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